DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0091]

Draft Guidance for Industry on User Fee Waivers for Fixed Dose Combination Products and Co-Packaged Human Immunodeficiency Virus Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR." This draft guidance describes the circumstances under which certain applications for fixed dose combination (FDC) and copackaged versions of previously approved antiretroviral therapies for the treatment of human immunodeficiency virus (HIV) under the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief (PEPFAR) will not be assessed user fees. The draft guidance also describes circumstances under which some of the applications that will be assessed fees may be eligible for a public health or a barrier-to-innovation waiver.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and

Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Michael Jones, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR." The draft guidance describes the circumstances under which certain applications for FDC and copackaged versions of previously approved antiretroviral therapies for the treatment of HIV under PEPFAR will not be assessed user fees. The draft guidance also describes circumstances under which some of the applications that will be assessed fees may be eligible for a public health or a barrier-to-innovation waiver.

As part of PEPFAR, FDA issued in May 2004 a draft guidance entitled "Fixed Dose Combination and Co-Packaged Drug Products for the Treatment of HIV" (Fixed Dose Guidance) (69 FR 28931, May 19, 2004). The Fixed Dose Guidance described some scenarios for approval of FDC or copackaged products for the treatment of HIV, provided examples of drug combinations considered acceptable for FDC/copackaging, and examples of those not

considered acceptable for FDC/copackaging. The draft guidance also explained that the Federal Food, Drug, and Cosmetic Act provides for certain circumstances in which FDA can grant sponsors a waiver or reduction in fees. The draft guidance also stated that the agency was evaluating the circumstances under which it may grant user fee waivers or reductions for sponsors developing FDC and copackaged versions of previously approved antiretroviral therapies for the treatment of HIV. Since issuance of the Fixed Dose Guidance, several potential applicants have asked that we clarify whether sponsors submitting drug applications under the Fixed Dose Guidance and under the PEPFAR program will be required to pay user fees under the Prescription Drug User Fee Act (PDUFA) and if so, whether they would be eligible for a waiver of those fees. As explained in this draft guidance, in some of the scenarios described in the Fixed Dose Guidance, a sponsor could qualify for fee exemptions or would only be assessed a half-fee either because the sponsor is using an active ingredient that has already been approved or the application does not require clinical data for approval. A sponsor of an application that would be assessed either a full- or a half-fee may also qualify for a waiver of the application fee under several provisions of PDUFA.

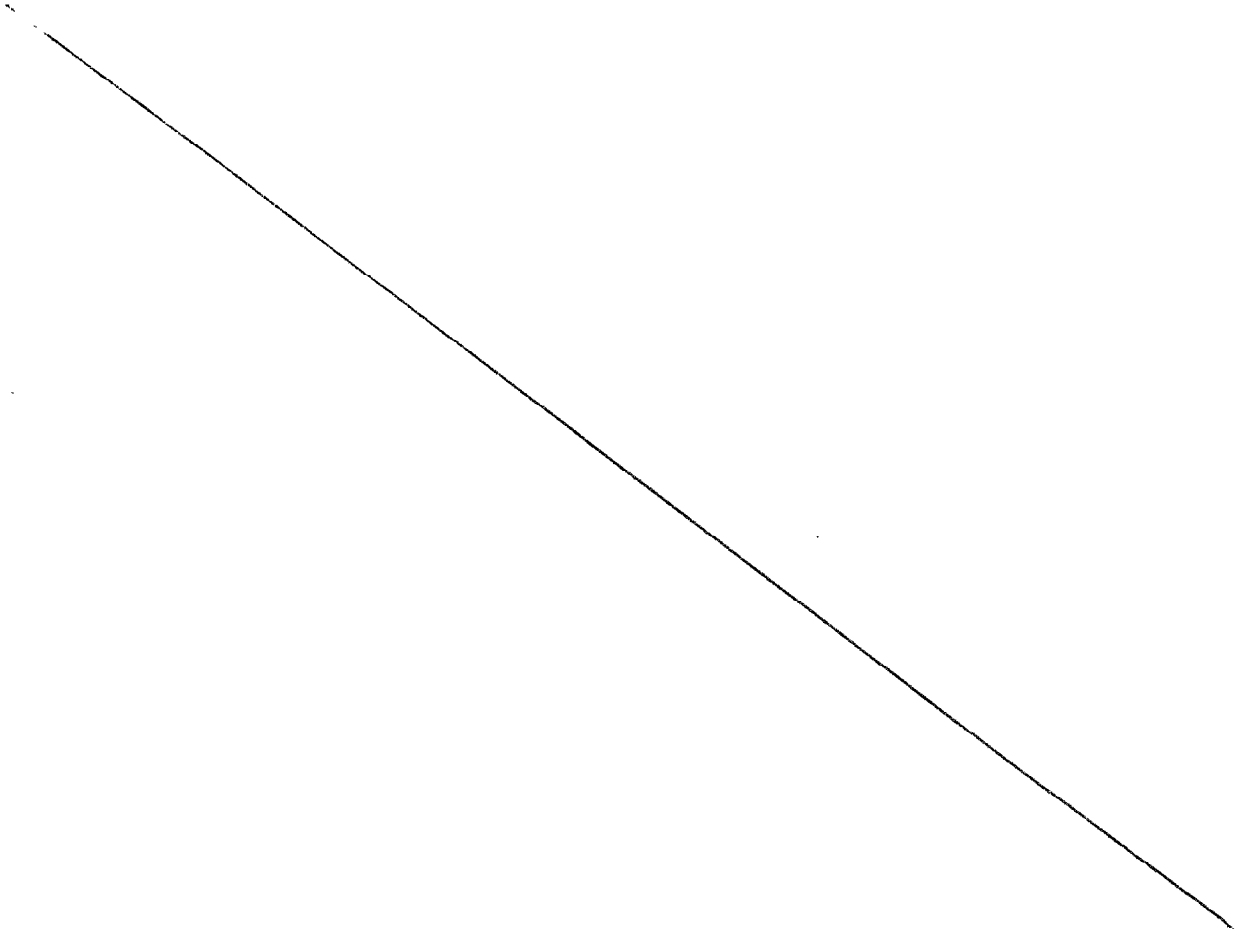
We expect that most of the applications, products, and establishments for FDC and copackaged HIV therapies proposed for use in the PEPFAR program will either not be assessed fees in the first instance or will qualify for a waiver under the special circumstances part of the barrier-to-innovation user fee waiver.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on waivers of user fees for FDC and

copackaged products for the treatment of HIV under PEPFAR. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: 4/13/05
April 13, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

BILLING CODE 4160–01–S